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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,108	04/05/2001	Stephen K. Sundquist	P-9327.00	5008
27581	7590	01/04/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/827,108	Applicant(s) SUNDQUIST ET AL.	
	Examiner Mark W Bockelman	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12,14,16-18,21-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12,14,16-18,21-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1, 3-10, 12 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed October 1, 2004. In that paper, applicant has stated "Claim 1 includes 'a coupling member..... Thus, an 'electrode assembly' is an unambiguously, positively recited element of the claim", and this statement indicates that the invention is different from what is defined in the claim(s) because claim 1 is recites the electrode assembly with in an intended use, functional statement rather than positively reciting the element as part of the invention. As stated in MPEP 2173.05(g) "A functional limitation is an attempt to define something by what it does rather than what it is". The examiner stands by his position that the electrode assembly is a hypothetical element to which applicant intends to use his balloon catheter with a coupler attached can be used with.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonner et al USPN 5,902,331.

Applicant's claim 1 recites a guiding device with an expandable fixation member and a coupling member with statements of intended use regarding a "hypothetical" electrode lead, regarded as "hypothetical" because the electrode lead is not positively recited in the claim. As noted in previous office actions Bonner et al show (e.g. fig 6) an elongate guiding device 150 with a distal end 154 having an expandable balloon 152 which is (capable of acting as an expandable fixation member as applicant's balloon), a coupling member 70 and electrode assembly 12 with tines as a fixation means (or helix –fig 7). The coupling member may be fastened to the guiding device to form a unified member. The coupling member is considered to be a rail, in the broadest meaning of the word permitted by Webster's dictionary. The couple assembly can itself be considered to be a rail having a rail extension 62 flexible enough to open to receive the catheters which, when held properly keeps the electrode assembly from twisting (about the guide) during slidable engagement (i.e. upon retraction –column 15 lines 30-40). The examiner notes that the guiding catheter has a guidewire lumen extending there through (column 15 lines 62-67) which is capable of delivering fluids (claim 8-10) and the balloon lumen "included" in the coupling member since it passes through the

coupling member lumen 68. The port at 154 is proximal (i.e. proximate) the balloon member.

Applicant's claims as amended on April 8, 2004 provides more functional language based upon how a "hypothetical" electrode lead would couple and uncouple to the guiding device. The examiner believes that one could envision a "hypothetical" lead to be used with the Bonner guiding member wherein the diameter (see reference numeral 12) of Bonner et al is approximately the same size as the coupling member lumen, and the wire 13 is of sufficient rigidity to disengage the lead by advancing the lead beyond the terminal end of the member 74. Thus, the guide member 156 of Bonner et al is considered "capable" of performing applicant's intended use and thus meets all of the limitations of the claim.

Claims 1, 3, 5-10, 12, 14, 16-17, 21-23, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Landberg et al USPN 6,527,769 or Lesh USPN 5,971,983.

Landberg et al show on the front cover, a guiding member 380, with a balloon 384 and a port 338 or 378 capable of delivering fluids. A coupling member 312 in the form of a rail slidably engages an electrode assembly 314, which has a fixation member 386 thereon. When optional stops 362 are not provided the electrode lead, can be disengaged by sliding the the electrode lead off of the coupling member terminal end. Notwithstanding, with regard to at least claim 1, which describes the interaction with a "hypothetical" electrode, one could easy envision an electrode member that engages lumen 376 (serving as a coupler) and can be disengaged by moving the hook member

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forward. Thus, it is capable of acting in a manner recited by applicant with other electrode lead members.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by VandenEinde et al USPN 5,415,639.

VandenEinde et al show a balloon catheter guide member with a coupler 314 (and or 302) for slidably engaging a guidewire. Applicant's recited intended use of the device with an electrode assembly fails to distinguish over VandenEinde since VandenEinde could potentially use an electrode assembly guidewire as that described in Hofmann et al USPN 5,704,908 that has a reduced diameter portion as in Bonner et al USPN ,5902, 331 to slidably disengage the electrode member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 14, 16-18, 21-23 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over or Bonner et al USPN 5,902,331.

In regards to claims 14, 16-17, 21-23 and 25, the examiner has addressed the structural limitations in previous office actions and refers applicant to those earlier office actions. In terms of the new "structure" in the form of functional language added to claim 14, the examiner is of the position that the electrode lead of Bonner could be disengaged by pushing the lead member 12 out of the coupler 76 when the balloon member 152 is inflated slightly so that a small frictional force retains the lead in the coupler. While the examiner recognizes that Bonner discloses his electrode wire to be *preferably* "limp" in column 12 lines 39-65, Bonner also recognizes that the wire may be of sufficient rigidity to screw the helix into the tissue after it is released by the guiding member (Column 8 lines 3-5). The examiner believes that a wire that is of sufficient rigidity to be rotated to screw a helix into tissue would be of sufficient rigidity to push the member out from the coupler when the coupler grasping is adjusted. If not inherent, it would be obvious to aid in its release. Therefore the examiner believes that the Bonner device is capable of acting in a fashion as claimed by applicant in his functional statements. The balloon member is capable of being used as an anchoring means AND is capable of aiding deploying the electrode device it is in the vasculature.

In regards to claims 4 and 18, while applicant recites rails such as H-rail and K-rail, it is unclear if this intended to be the shape of the rail or not. In this regard, the Bonner rail is considered to be each of these types of rails, or otherwise the double clamp forms a general h-shape rail. Alternatively, to shape the rail member of Bonner in any shaped desired that still form the function of joining the electrode assembly to the balloon containing guide member would have been obvious design choice.

Response to Arguments

Applicant's arguments filed 10-01-2004 have been fully considered but they are not persuasive. Applicant continues to provide and argue intended use language that the references merely need to be capable of performing, which the examiner has demonstrated above. With respect to applicant's comments regarding Landberg et al relevance. While the examiner agrees that the reference has little to do with applicant's invention **as disclosed in his specification**, the examiner also notes that the claims are drafted in such a way that would cover the Landberg et al device as well. Applicant has not even stated in the claims that the coupling member is attached to the guiding member, only that it is adjacent to it. The claims only recite that the electrode lead is coupled to the coupling member.

As noted above by the examiner, functional language is an attempt to define the invention by what it does rather than what it is. Much of applicant rebuttal is drawn to whether or not the language is improper under 112 second paragraph in terms of clarity, to which the examiner notes no rejection is made, The examiner does not consider the language to be improper, but considers it to be treated as intended use, i.e. as to what the device does.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB

December 27, 2004


MARK BOCKELMAN
EXAMINER